

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0999952	<b>(X3) Date Survey Completed</b> 05/03/2023
<b>Name of Provider or Supplier</b> Novant Health Cancer Institute Matthews	<b>Street Address, City, State</b> 1700 Matthews Township Parkway, Matthews, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2020, 2021, 2022 and 2023 maintenance records for the ACE Axcel chemistry analyzer and interview with technical consultant (TC) 5/3/23, the laboratory failed to document the bi-annual maintenance for approximately 33 months or 5 of 5 times required. Findings: Review of laboratory procedure "ACE Axcel Chemistry Analyzer" revealed "MAINTENANCE...Bi-Annual Maintenance 1. Replace ISE tubing.". Review of 2020, 2021, 2022 and 2023 ACE Axcel maintenance records revealed no documentation of the performance of bi-annual maintenance since testing began in July of 2020. Interview with TC at approximately 12:00 p.m. confirmed the bi-annual maintenance of the ACE Axcel analyzer was not documented. She stated the maintenance is performed as part of the calibration verification procedure, but they must have forgot to document it on the maintenance logs.</p>
<b>D5891</b>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory postanalytic quality assessment (QA) policies, review of laboratory records and interview with TC 5/3/23, the laboratory failed to establish a QA policy or procedure for a periodic verification of calculated chemistry results. Findings: Review of laboratory QA policies and records revealed the laboratory performs multiple postanalytic quality assessments, including the review and transfer of results to the laboratory information system (LIS). The QA policies failed to include a policy or procedure for a periodic verification of calculated chemistry results. For example; Albumin/Globulin Ratio, Bun/Creatinine Ratio and Glomerular Filtration Rate. Review of laboratory records revealed the laboratory performed a verification of calculated chemistry results when the chemistry analyzer was installed in July of 2020. There was no documentation of a periodic verification of calculated results since July of 2020. Interview with TC at approximately 12:30 p.m. confirmed the laboratory had not performed a periodic check of the chemistry calculation since the analyzer was installed in July of 2020.